REMARKS

Responsive to the Notice of Non-Compliant Amendment (37C.F.R. §1.121) mailed January 6, 2005, Applicants submit a revised Response to the Office Action mailed July 14, 2004. The revised Response has been changed to reflect a complete listing of all the claims. Entry of the amendments and remarks contained in the Response filed herewith is respectfully requested.

Claims 1-27 are pending. Claims 8 and 10-27 have been cancelled without prejudice. Claim 1 has been amended to incorporate the elements of dependent claim 8. Accordingly, the amendment does not raise an issue of new matter. Following entry of the amendments, claims 1-7 and 9 will be pending and under examination. Applicant has reviewed the rejections set forth in the Office Action and respectfully traverse all grounds for the reasons that follow.

Rejections Under 35 U.S.C. § 112

Claims 10-18 stand rejected under 35 U.S.C. § 112, first paragraph, for lacking written description allegedly because they fail to recite the environment of the claimed nerve cell. The Office asserts that the application describes the therapeutic treatment of mammals but that the claims neither recite the enhancement of a neuron *in vivo* or treatment in mammals. It is suggested that these claims be amended to recite enhancement of nerve cells in mammals to overcome this ground of rejection.

Applicant maintains that claims 10-18 are adequately described in the application as filed. Nevertheless, to further prosecution of this application, claims 10-18 have been cancelled without prejudice. Accordingly, this ground of rejection is moot and withdrawal is respectfully requested.

Claims 19-27 remain rejected and claims 10-18 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement for the full scope of the claimed invention. The Office maintains that the invention is enabled for promoting survival in humans of the specific neurons described in the Examples, entorhinal layer II neurons, nigral-TH positive neurons and spinal motorneurons. However, the Office maintains that *in vivo* gene therapy was unpredictable at the time of filing and that the claimed retrograde delivery constitutes only one aspect of the claimed method. Orkin et al.(Orkin and Mogulsky, Report and Recommendations of teh Panel to Assess the

NIH Investment in Research on Gene Therapy (December 7, 1995), Verma et al. (Nature 389: 239-242 (1997)) and Rosenberg et al. (Science 287:1751 (2000)) are relied upon as support for the Office's conclusion that the invention lacks therapeutic enablement.

Applicant maintains that the full scope of claims 10-27 is sufficiently enabled by the application as filed. Nevertheless, to further prosecution of this application, claims 19-27 have been cancelled without prejudice. Accordingly, this ground of rejection is moot and withdrawal is respectfully requested.

Claim 12 stands rejected under 35 U.S.C. § 112, second paragraph, for being indefinite allegedly because it is unclear how the term "incubating" in claim 10 relates to the invention. Claim 17 remains rejected under 35 U.S.C. § 112, second paragraph, for being indefinite allegedly because the term "a nerve growth factor" is unclear. The Office maintains that nerve growth factor refers to the specific factor termed NGF. Applicant maintains that claims 12 and 17 are sufficiently clear to distinctly claim the subject matter Applicant regards as the invention. Nevertheless, to further prosecution of this application, claims 10and 17 have been cancelled without prejudice. Accordingly, these grounds of rejection are moot and withdrawal is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 10-12 and 16 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Peterson et al. (Euro. J. Neurosci. 12: (Supp.) 233) (2000).

Applicant maintains that Peterson et al. do not anticipate claims 10-12 and 16. Nevertheless, to further prosecution of this application, claims 10-12 and 16 have been cancelled without prejudice. Accordingly, this ground of rejection is moot and withdrawal is respectfully requested.

Claims 1, 2, 4-7, 19, 20 and 22-25 remain rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by Horellou et al., US 2002/0031493, or by Finiels et al., U.S. Patent No. 6,632,427. The Examiner alleges that Horellou et al. and Finiels et al. are directed, in part, to the treatment of human neurological diseases, which "would mean that humans are to be treated and human neurons are to be transfected." The description at paragraph 0048 and claim 29 in Horellou

et al. is cited as support for this assertion and columns 1-2 and column 13, lines 8-41 in Finiels is cited is cited as support. The Office further states that claims 10, 12-15 and 17 are not directed to human neurons.

Claims 10-27 have been cancelled without prejudice. Therefore, any rejection of these claims is moot.

Claim 1 is directed to a method for transducing a human neuron having a synaptic portion and a cellular portion with a heterologous gene. The method includes contacting the synaptic portion of the human neuron with a viral vector containing a heterologous gene under conditions that result in transduction of the viral vector into the synaptic portion and retrograde movement of the viral vector from the synaptic portion to the cellular portion. The heterologous gene is incorporated into the genome of the human neuron and expressed for at least two months.

Neither Horellou et al. or Finiels et al. describes the expression of a transduced gene for at least two months. The Office appears to concede this distinction because this claim is not rejected over the cited art. Because neither Horellou et al. nor Finiels et al. describes expression of a transduced gene for at least two months, claim 1 is distinguishable from, and not anticipated by, the cited art. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 1-4, 8, 9, 19-21 and 25-27 remain rejected under 35 U.S.C. § 103(a) as allegedly obvious over Peterson et al. The Office alleges that one skilled in the art would have expected the animal models of Peterson et al. to work in humans.

Applicant maintains that claims 19-21 and 25-27 are unobvious over the cited art, especially in light of the uncertainties raised by Peterson et al. and set forth in Applicant's previous response. Nevertheless, to further prosecution of this application, these claims have been cancelled without prejudice. Accordingly, this ground of rejection is moot as to claims 19-21 and 25-27 and withdrawal is respectfully requested.

Regarding claims 1-4, 8 and 9, Applicant maintains that these claims are neither taught or suggested by Peterson et al. To establish *prima facie* obviousness of a claimed invention, all the

claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (C.C.P.A. 1974); M.P.E.P. §2143.03. Further, the combination of elements must have been suggested to one of ordinary skill in the art and that it could have been carried out with a reasonable likelihood of success when viewed in the light of the prior art. *Brown & Williamson Tobacco v. Philip Morris*, 229 F.3d 1120, 1124 (Fed. Cir. 2000).

Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness at least because all the elements of the claimed method for transducing a human neuron are neither taught or suggested by the cited art, nor is there a reasonable expectation of success that the claimed invention could have been carried out based on the cited art. The pending claims recite transducing a human neuron and retrograde movement of the viral vector from the synaptic portion to the cellular portion wherein a heterologous gene is incorporated into the genome of the human neuron and expressed for at least two months. Peterson et al. do not teach or suggest a human neuron, incorporation into the genome of a human neuron and expression of a heterologous gene for at least two months.

Peterson et al. appear to describe that hippocampal neurons were found to be infected at the site of injection in rat and further describe expression of green fluorescent protein (GFP). Peterson et al. specifically state that it is unclear whether virus or protein might have been transported and hypothesize merely that the treated rat neurons might have the capacity for retrograde transport. In this regard, Peterson et al. raise uncertainties as to how and where expression might have occurred because they conclude that the observed results could be due to transport of the either the protein or of the virus. Further, Peterson et al. does not teach or suggest expression of the heterologous gene for at least two months.

Peterson et al. fail to teach or suggest the invention method as claimed. Because Peterson et al. does not teach or suggest all of the claimed elements, Peterson et al. cannot render obvious Applicant's claimed invention. Therefore, withdrawal of this ground of rejection is respectfully requested.

Provisional Doubling Patenting

Claims 1-27 stand provisionally rejected under the doctrine of obviousness-type double patenting of claims 1-26 of co-pending application no. serial number 10/237,567. Because this rejection is provisional and the allegedly conflicting claims have not in fact been patented, Applicant respectfully requests deferral of this ground of rejection until there is an indication of allowable subject matter in one or both applications.

CONCLUSION

In light of the Amendments and Remarks herein, Applicant submits that the claims are in condition for allowance and respectfully requests a notice to this effect. Should the Examiner have any questions, he is invited to call the undersigned attorney

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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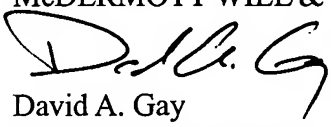

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